

REMARKS

Formal Matters

Claims 1-32 are pending in the application. Claims 17-32 are withdrawn from consideration. Claims 1-16 were examined and rejected.

Claim 1 has been amended to clarify that a non-cellular chromosome composition is made by mixing pre-determined amounts of individual mammalian chromosomes. Support for this amendment can be found in the specification on, e.g., page 15, line 5.

Claim 3 has been amended to clarify that the surface bound polynucleotides bind to a polynucleotide sequence that is present in a chromosome that is present in both the non-cellular and reference chromosome compositions. Support for this amendment can be found in the specification on, e.g., page 16, line 15.

Claim 15 has been amended to state that the chromosomal composition probes are made using a chromosome composition comprising all chromosomes of an animal cell.

As no new matter has been added by way of this amendment, entry thereof by the Examiner is respectfully requested.

In view of the following remarks, the Examiner is requested to allow claims 1-16, the only claims pending and under examination in this application.

Claim Rejections – 35 U.S.C. § 112

Claims 1-16 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claiming the subject matter which applicant regards as the invention.

Without any intention to acquiesce to the correctness of this rejection and solely to expedite prosecution, claim 1 is amended to recite mixing pre-determined amounts of individual mammalian chromosomes to produce a non-cellular chromosome composition as a separate step. The Applicants submit that this aspect of the rejection has been addressed.

Without any intention to acquiesce with this rejection and solely to expedite prosecution, claim 3 is amended to recite that the surface-bound polynucleotide binds to a polynucleotide sequence that is present in a chromosome that is present in both the non-cellular and reference chromosome compositions. The Applicants believe that this aspect of the rejection has been addressed.

Claim 4-8 are rejected as indefinite as they allegedly do not further define the method of claim 1. The Applicants respectfully disagree. Claim 4 states a method of claim 3, wherein said chromosome is present at a predetermined ratio in the non-cellular and reference chromosome compositions. Claim 3 depends on claim 1 which states a method of mixing pre-determined amounts of individual mammalian chromosomes to produce a non-cellular chromosome composition. Hence, claim 4 specifies that a chromosome is present at a pre-determined ratio in the non-cellular and reference chromosome compositions. Since claim 1 does not recite a requirement for pre-determined ratios, and claim 4 does recite such a requirement, claim 4 is different in scope to claim 1.

Claim 15 is amended to specify that the chromosome composition probes are made using a chromosome composition comprising of all chromosomes of an animal cell. It is believed that this aspect of the rejection is now moot.

The Applicants submit that this rejection may be withdrawn.

Claim Rejections – 35 U.S.C. § 102 (a): Lucito et al

Claims 1-16 are rejected under 35 U.S.C. 102(a) as being allegedly anticipated by Lucito (Genome Research, published 15 September 2003, 13: 2291-2305). The Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Additionally, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1566 (Fed. Cir. 1990).

Claim 1 has been amended to recite a method that requires: “mixing pre-determined amounts of individual mammalian chromosomes to produce a non-cellular chromosome composition”.

The Applicants submit that this element is not disclosed by Lucito. As such, Lucito cannot anticipate the claims and this rejection should be withdrawn.

Lucito (page 2304, first paragraph) describes a method of labeling DNA but does not disclose that the labeled population is made from non-cellular chromosome composition that is synthesized by mixing predetermined amounts of individual chromosomes. Since mixing pre-determined amounts of individual mammalian chromosomes to produce a non-cellular chromosome composition is not disclosed in Lucito, Lucito et al cannot anticipate the claims.

Further, in attempting to reject Claim 10, the Applicants note that the Examiner states that Lucito discloses isolating chromosomes from mammalian cells to provide a chromosomal composition on page 2295, right column, first full paragraph. However, Lucito does not describe isolating a chromosome from a mammalian cell in this section. Rather Lucito discloses a method comprising separating the nuclei of a surgical biopsy into aneuploid and diploid fractions. Lucito’s method does not teach isolating individual chromosomes.

Since Lucito does not teach each and every element of claims 1-16, Lucito does not anticipate any of the rejected claims. As such, this rejection should be withdrawn. Withdrawal of this rejection is requested.

Claim Rejections – 35 U.S.C. § 102 (b): Burchard (WO 01/06013)

Claims 1-9, 11, 14 and 16 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Burchard (WO 01/06013, published 25 January 2001). The Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Additionally, the identical invention

must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1566 (Fed. Cir. 1990).

Claim 1 has been amended to recite a method that requires: "mixing pre-determined amounts of individual mammalian chromosomes to produce a non-cellular chromosome composition".

The Applicants submit that this element is not disclosed by Burchard and as such Burchard cannot anticipate the claim.

Burchard discloses labeling nucleic acids made from genomic DNA. However, the genomic DNA or the other sources of a population of nucleic acids taught in Burchard are not obtained from a step of mixing pre-determined amounts of individual mammalian chromosomes.

Since Burchard does not teach a method of mixing pre-determined amounts of individual mammalian chromosomes to produce a non-cellular chromosome composition, Burchard does not anticipate claims 1-16. Hence, withdrawal of the 102(b) rejection for claims 1-16 is respectfully requested.

Claim Rejections – 35 U.S.C. § 103: Snijders in view of Burchard

Claims 1-16 are rejected under 35 U.S.C. 103(a) as supposedly being unpatentable over Snijders (*Nature Genetics*, 2001, 29: 263-264) in view of Burchard (WO 01/06013, published 25 January 2001).

The Patent Office has recently published guidelines for determining obviousness under 35 U.S.C. §103 in view of the KSR decision. These guidelines, termed the "Obviousness Guidelines" are found in the Federal Register Vol. 72, No. 195 (published Wednesday, October 10, 2007) and should be followed by Examiner in evaluating whether a claim is obvious.

According to the Obviousness Guidelines, when Office personnel reject claims by attempting to combine prior art elements according to allegedly known methods to yield predictable results, the Office must resolve the Graham factual inquiries and articulate:

(1) "a finding that **the prior art included each element claimed**, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;"

(2) "a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately; and"

(3) "a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable." (Federal Register / Vol. 72, No. 195 / Wednesday, October 10, 2007 / Notices at 57529, *citing KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (US 2007).

Thus, the rationale to support a conclusion that a claim would have been obvious is that "all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions," and that "the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention." *Id.* at 57529.

Claim 1 has been amended to recite a method of assessing a surface-bound polynucleotide comprising mixing pre-determined amounts of individual mammalian chromosomes to produce a non-cellular chromosome composition. The Applicants submit that neither of the cited references teach or suggest this element and as such this rejection should be withdrawn.

Snijders describes a method that does not teach mixing pre-determined amounts of individual mammalian chromosomes. The chromosome samples described are simply extracted from cell lines and, as such, they are neither made by mixing individual chromosomes, nor mixing pre-determined amounts of individual chromosomes, as required by the rejected claims.

As noted above in the prior section of this response, Burchard is also deficient in that it fails to teach or suggest any method that includes mixing pre-determined amounts of individual mammalian chromosomes.

As such, Snijders and Burchard, taken in any combination, fail to teach or suggest any method that includes mixing pre-determined amounts of individual mammalian chromosomes, as required by the rejected claims.

Thus, the combination of Snijders and Burchard does not make claims 1-16 obvious. Hence, rejection of claims 1-16 under 35 U.S.C. 103(a) should be withdrawn.

CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone James Keddie at (650) 833-7723.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10031034-1.

Respectfully submitted,

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